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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,783	09/23/2003	Miroslav Smriga	241244US0CONT	9560
22850	7590	06/28/2011	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			06/28/2011	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/667,783	<b>Applicant(s)</b> SMRIGA ET AL.
	<b>Examiner</b> LEZAH ROBERTS	<b>Art Unit</b> 1612

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,14,16-26 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-10, 14, 16-23 and 30-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
|--|--|

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## **DETAILED ACTION**

Applicants' arguments, filed in the Request for Continued Examination on August 30, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant has elected anxiety disorders in the reply filed October 25, 2006. During the course of Examination, all species but irritable bowel syndrome have been deleted. The Examiner has extended prosecution to irritable bowel syndrome.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

Claims 1, 2, 5-10, 14, 16-23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (Pediatrics in Review, 1981) in view Kobayashi et al. (JP 58088323)

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Walker discloses chronic nonspecific diarrhea or infancy (CNSD) or irritable bowel syndrome represents one of the most common gastrointestinal problems confronted by practicing pediatricians.

The reference differs from the instant claims insofar as it does not disclose the CNSD or IBS is treated with a lysine salt form with glutamic acid.

Kobayashi et al. disclose a nutritive composition for infants comprising amino acids such as L-lysine and L-arginine. Lysine comprises 7.14 to 9.66% of the total amino acids (0.357% to 1.546% of the total composition encompassing claim 18) and arginine comprises 4.33 to 5.85 % of the total amino acids. The amino acids comprise 5 to 16 weight % of the composition. Other amino acids include L-aspartic acid and L-glutamic acid, encompassing claims 6-10. It is preferred that some lysine and arginine are used as lysine glutamate and arginine glutamate. The compositions also include minerals, encompassing claim 22. The compositions are prepared as powders and are administered orally by dissolving in water or milk. The compositions are used for infantile diarrhea and dyspepsia, which is interpreted to encompass abnormal gastric motion (see Abstract).

The reference differs from the instant claims insofar as it does not disclose the compositions are used to treat irritable bowel syndrome.

In KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try"

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such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to treat irritable bowel syndrome. Accordingly, it would have been obvious to have treated irritable bowel syndrome of Walker with the compositions of Kobayashi et al. comprising lysine glutamate motivated by the desire to use a composition disclosed in the art as being effective for treating diarrhea, a symptom of IBS in infants.

In regard to claims 16 and 17, Kobayashi et al. disclose the amount of the lysine but does not disclose the dose of lysine. It would have been in the relative skill of one of ordinary skill in the art to have determined the effective amount of lysine needed to get the desired effect. Thus, it would have been obvious to one of ordinary skill in the art to have administered 0.0001 to 13g/kg/body weight daily of a lysine motivated by the desire to obtain optimal efficacy of the disclosed composition.

Claims 1, 2, 5-10, 14, 16-23 and 30-32 are rejected.

Claims 15 and 24-26 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612